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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,766	04/29/1999	EIJIRO WATANABE	0020-4559P	6045
2292	7590	05/14/2004	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/301,766

**Applicant(s)**

WATANABE ET AL.

**Examiner**

David H Kruse

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 16-23 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. This Office action is in response to Applicant's amendments and arguments filed 11 February 2004.
2. This Office action is non-final in view of issues not previously addressed by the Examiner.
3. The Watanabe Declaration filed under 37 C.F.R. § 1.132 on 11 February 2004 is acknowledged and is addressed herein.
4. Those rejections not specifically addressed in the Office action are withdrawn in view of Applicant's amendments to the claims.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

6. The specification is objected to because the Brief Summary of the Invention, starting on page 2 of the specification filed 14 April 2000, consists of a listing of claims and does not comply with 37 C.F.R. § 1.73. See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 C.F.R. § 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the

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inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

7. The disclosure is objected to because of the following informalities:

In the specification filed 14 April 2000, pages 50 and 51, Applicant states that SEQ ID NO: 1 & 2 describe a broad bean raffinose synthase gene (RSG), SEQ ID NO: 3 & 4 describe a soybean RSG, SEQ ID NO: 5 & 6 describe a Japanese artichoke RSG, SEQ ID NO: 7 & 8 describe a corn RSG. The paper copy of the sequence listing filed 29 April 1999 and the CRF entered 12 January 2000 states that SEQ ID NO: 1 & 2 describe a soybean RSG, SEQ ID NO: 3 & 4 describe a beet RSG, SEQ ID NO: 5 & 6 describe a *Brassica juncea* RSG, SEQ ID NO: 7 & 8 describe a *Brassica napus* RSG. The first page of the Raw Sequence Listing of record is attached hereto.

Example 6 on page 37 of the specification describes isolation of broad bean cDNA encoding a putative RSG, and states that it is described in SEQ ID NO: 1, while the sequence listing states that SEQ ID NO: 1 describes a *Glycine max* (soybean) cDNA.

Example 9 on pages 41 and 42 describe isolation of a soybean cDNA encoding a putative RSG, and states on page 42 SEQ ID NO: 3 describes said cDNA, while the sequence listing states that SEQ ID NO: 3 describes a beet cDNA.

Example 10 on page 43 describe isolation of a Japanese Artichoke cDNA encoding a putative RSG, and states on page 43 SEQ ID NO: 5 describes said cDNA, while the sequence listing states that SEQ ID NO: 5 describes a *Brassica juncea* cDNA.

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Example 11 on page 44 describe isolation of a corn cDNA encoding a putative RSG, and states on page 44 SEQ ID NO: 7 describes said cDNA, while the sequence listing states that SEQ ID NO: 7 describes a *Brassica napus* cDNA.

Hence, the specification is objected to because the description in the specification does not describe what is disclosed in the paper copy of the Sequence Listing or in the filed CRF.

Applicant is advised to avoid entry of new matter into the specification and/or the claims.

***Claim Rejections - 35 USC § 101***

8. Claims 1-10, 16-23 and 28-30 remain rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 August 2003. Applicant's arguments filed 11 February 2004 have been fully considered but they are not persuasive.

Applicant argues that the Eijiro Watanabe Declaration, filed 11 February 2004 shows that the claimed nucleic acids are indeed raffinose synthase genes (pages 11-12 of the Remarks). The Watanabe Declaration under 37 CFR § 1.132, filed 11 February 2004, is insufficient to overcome the rejection of claims 1-10, 16-23 and 28-30 based upon lack of a substantial asserted utility or a well-established utility under 35 U.S.C. § 101 as set forth in the last Office action because said declaration does not specifically teach which *Brassica* nucleic acid is used in the experiments, *Brassica juncea* and *Brassica napus* can both be considered a mustard. In addition, given the issue outlined

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supra as to what is described in the specification, it is unclear if the filed declaration can be used to establish the utility of the claimed isolated nucleic acids and methods of using same.

Applicant argues that it (the Watanabe Declaration) unequivocally shown that the claimed nucleic acids of the present invention express raffinose synthase activity in a transformed plant (page 12 of the remarks). This is not found to be persuasive because the Declaration only provides evidence of function, and thus utility, of a nucleic acid isolated from mustard, and does not establish the utility of the invention as broadly claimed.

The Examiner clarifies the teachings of the specification outlined in the previous Office action on page 3. Applicant teaches transforming a *Brassica juncea* plant with a broad bean raffinose synthase gene in Example 13 on pages 46-48, but provides no evidence of function in the transformed plant. Applicant's Example 9 previously discussed does not teach transforming a plant with a putative *Brassica* raffinose synthase gene.

In addition, SEQ ID NO: 2 and 8 disclose partial coding sequences, hence, the claims directed to these partial coding sequences lack a substantial asserted utility (see claims 1-3, 8, 9, 16-23 and 28-30).

***Claim Rejections - 35 USC § 112***

9. Claims 1-10, 16-23 and 28-30 also remain rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above,

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one skilled in the art clearly would not know how to use the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 August 2003. Applicant's arguments filed 11 February 2004 have been fully considered but they are not persuasive. Applicant's argument directed to the second enablement rejection are also addressed herein.

Applicants argue that the homologies among RFSS are higher than those homologies between RFSS and SIPs and between RFSS and STSS and that the skilled artisan could rely on homology to determine whether or not a nucleic acid would actually encode a raffinose synthase enzyme (page 14 of the Remarks). This argument is not found to be persuasive because even at 50% sequence similarity, one of skill in the art at the time of Applicant's invention could not assume that a nucleic acid encoding a raffinose synthase whose function is solely based on sequence homology would have the asserted function without a reduction to practice to establish raffinose synthase function. At the time of Applicant's invention, the Examiner is only aware of one other plant nucleic acid encoding a raffinose synthase, having been isolated from cucumber. The Examiner has reviewed Tables 1 and 2 of the Appendix filed with the instant response. While Table 2 shows a variation of between 50-70% identity among the putative and/or confirmed RFSS enzymes at the amino acid level, and between 34-45% identity between the putative and/or confirmed RFSS enzymes and STSS enzymes at the amino acid level, this does not establish that simply based on sequence similarity that one of skill in the art can assert function. Using the BLAST function of NCBI, the *Stachys affinis* stachyose synthase has 51% sequence identity with the *Pisum sativum*

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raffinose synthase (Accession No CAD20127) and 50% sequence identity with the *Cucumis sativus* raffinose synthase (Accession No AAD02832). These levels of sequence identity are well within the range of sequence identity among the putative and/or confirmed RFSS enzymes at the amino acid level (NCBI can be found at [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov), see attached NCBI/BLAST search report). Hence it is unclear how Applicant can assert function based on only one other raffinose synthase gene known in the art, without empirical evidence for such function. In addition, neither the art nor Applicant teaches any special structural feature of a raffinose synthase that distinguishes species of the genus from other enzymes, such as stachyose synthase.

Applicant argues that Table 2 and Figure 1 show that RFSS, SIPs and STSS can be easily distinguished from one another based upon a comparison of their amino acid sequences and that contrary to the Examiner's opinion, amino acid sequence similarity can be used to assert function (page 14 of the Remarks). This argument is not found persuasive for the reasons given above.

Applicant argues that the homologies between raffinose synthase enzymes and seed imbibition proteins or stachyose synthases are considerably lower than homologies among raffinose synthase enzymes and thus one of skill in the art could predict the function of a nucleic acid based upon its sequence similarity with known raffinose synthase enzymes (page 19 of the Remarks). Applicant argues that in the present case, there is a high level of skill in the art (e.g., a Ph.D. in biochemistry or its equivalent), the specification provides considerable direction, guidance and teaches the methods needed to practice invention are known, thus, it would not cause the skilled



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artisan undue experimentation to make or use the (page 20 of the Remarks). This argument is not found to be persuasive because without adequate guidance by Applicant on how to make and use the claimed nucleic acids it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to verify Applicant's claimed invention and to make and use other sequences that hybridize to said sequences as broadly claimed. Applicant appears to put the burden on others to teach one of skill in the art how to make and use the invention. The issue of asserting function of an encoded raffinose synthase based on sequence similarity with another has been addressed supra.

In addition, SEQ ID NO: 1, 2, 7 and 8 only teach partial amino acid and nucleic acid sequence and hence to not teach an isolated nucleic acid encoding a protein having raffinose synthase activity.

10. Claims 1-10, 16-23 and 28-30 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 August 2003. Applicant's arguments filed 11 February 2004 have been fully considered but they are not persuasive.

Applicant argues that the homologies between raffinose synthase enzymes and seed imbibition proteins or stachylose synthases are considerably lower than the

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homologies among raffinose synthase enzymes, thus, one of skill the art could describe a putative raffinose synthase based upon its sequence similarity with known raffinose synthase enzymes (pages 15-16 of the Remarks). This argument is not found to be persuasive because just because similarities are lower between raffinose synthase and stachyose synthase than among raffinose synthases, does not support an argument of function based on similarity (homology). In addition, such an assertion could not have been made based on what was known in the art at the time of Applicant's invention. Using the BLAST function of NCBI, the *Stachys affinis* stachyose synthase has 51% sequence identity with the *Pisum sativum* raffinose synthase (Accession No CAD20127) and 50% sequence identity with the *Cucumis sativus* raffinose synthase (Accession No AAD02832). These levels of sequence identity are well within the range of sequence identity among the putative and/or confirmed RFSS enzymes at the amino acid level (NCBI can be found at [www.ncbi.nlm.nih.gov](http://www.ncbi.nlm.nih.gov), see attached NCBI/BLAST search report).

Applicant argues that the Watanabe Declaration provides evidence of adequate written description (page 16 of the Remarks). This argument is not found to be persuasive because it is unclear what nucleic acid was used in the example as outlined above. In addition, the evidence for one nucleic acid does not adequately describe what function the other nucleic acids have as Applicant asserts.

Applicant argues that the disclosure in the instant specification is above and beyond what is required by the USPTO and exemplified in Example 9 and that the instant specification describes a plurality of isolated nucleic acids, which encode

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raffinose synthase (SEQ ID NOs: 2, 4, 6, and 8) (page 18 of the Remarks). This argument is not found to be persuasive. Example 9 describes isolation of a soybean cDNA having raffinose synthase activity, but the specification states that the sequence is described in SEQ ID NO: 3, where as the Sequence Listing states that SEQ ID NO: 3 describes a beet raffinose synthase. SEQ ID NO: 1 and 2 of the Sequence listing states that a *Glycine max* raffinose synthase is therein described, but the described sequence is incomplete and does not describe a complete protein.

In addition, the claims in general lack adequate written description because the plants and nucleic acids described in the specification do not match the description in the Sequence Listing of record, filed 29 April 1999. This issue is outlined in detail above under the objection to the specification. Also, SEQ ID NO: 1, 2, 7 and 8 only describe partial amino acid and nucleic acid sequence and hence to not describe an isolated nucleic acid encoding a protein having raffinose synthase activity.

11. Claims 1-10, 16-23 and 28-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the teachings of the specification do not appear to teach the specific sequences in the claims as outlined in detail above under the objection to the specification. Hence, the metes and bounds of the claimed invention are unclear in view of the teachings of the specification.

### ***Double Patenting***

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-3, 16-23 and 28-30 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 9, 30-36, 40, 41, 44 and 45 of copending Application No. 08/992,766. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims of the instant rejection are directed to an isolated nucleic acid encoding a raffinose synthase isolated from soybean, to which the indicated claims of the co-pending application are also directed.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.


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**Conclusion**

14. This Office action is non-final.
15. No claims are allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.



David H. Kruse

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David H. Kruse, Ph.D.  
12 May 2004